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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT J. GARABEDIAN, AMY C. KELLY, and STEVEN K. LANDREVILLE

Appeal 2008-0230
Application 10/606,250
Technology Center 3700

Decided: April 3, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a tissue ablation device which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

The Claims

Claims 23-29, 33-44, 48, 49, and 70-81 are on appeal. We will focus on claims 23, 35, 70, and 76 which are representative and read as follows:

> 23. A method of using an alignment device for performing a compound ablation in the body of a patient, the alignment device having a plurality of apertures, comprising:
>
> affixing an alignment device relative to targeted tissue, wherein the apertures are located external to the body;
>
> guiding an ablation probe within a first one of the externally located apertures to place the ablation probe adjacent the targeted tissue in a first region;
>
> operating the ablation probe to create a first lesion in the first region; guiding the ablation probe within a second different one of the externally located apertures to place the ablation probe adjacent the targeted tissue in a second region; and
>
> operating the ablation probe again to create a second lesion in the second region.
>
> 35. A method of using an alignment device for performing a compound ablation in the body of a patient, the alignment device having a plurality of apertures, comprising:
>
> affixing an alignment device relative to targeted tissue, wherein the apertures are located external to the body;
>
> guiding a plurality of ablation probes within respective ones of the externally located apertures to place the ablation probes adjacent the targeted tissue in a plurality of regions, and
>
> sequentially operating sets of the ablation probes to create a plurality of lesions in the plurality of regions.
>
> 70. The method of claim 23, wherein the ablation probe has a cannula and at least one electrode deployable from the

> cannula, the method further comprising deploying the at least one electrode from the cannula into the first region prior to creating the first lesion and deploying the at least one electrode from the cannula into the second region prior to creating the second lesion.
>
> 76. The method of claim 23, wherein the alignment device is affixed to skin of the patient.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Cosman	US 6,530,922 B2	Mar. 11, 2003
Morris	US 2002/0120261 A1	Aug. 29, 2002

The issues

The rejections as presented by the Examiner are as follows:

A. Claims 23-27, 29, 33-39, 44, 48, 49, and 70-81 stand rejected under 35 U.S.C. § 103(a) as obvious over Cosman.

B. Claims 28 and 40-43 stand rejected under 35 U.S.C. § 103(a) as obvious over Cosman and Morris.

A. 35 U.S.C. § 103(a) rejection over Cosman

The Examiner reasons regarding claims 23 and 35 that while

> Cosman may teach and adamantly hold that the creation of a single, larger lesion with a plurality of simultaneously actuated probes yields a superior result, this teaching does not mitigate the fact that it is known to create a larger lesion through the use of serially or sequentially activated probes.

(Ans. 6.)

The Examiner argues regarding claim 23, which is directed to a method of utilizing a single probe, that "one of ordinary skill in the art

would recognize that operating a single probe in a plurality of locations would be an obvious alternative to placing a plurality of probes and then activating the plurality of probes sequentially to create a plurality of lesions" as in Cosman (Ans. 7).

The Examiner also contends that while Cosman uses a "stereotactic guide to deliver the plurality of electrodes to treat very large lesions" (Ans. 8), Cosman also "specifically disclose[s] an embodiment (Figure 7) that includes a sheath, or cannula, to deploy a smaller number of electrodes to a tumor" (Ans. 8).

Appellant states that

> [w]hile Appellant does not disagree that it was known to serially or sequentially activate multiple probes to create multiple lesions (see background of present application), Appellant does disagree that one of ordinary skill in the art would have been motivated to modify the Cosman method in the manner suggested by the Examiner.

(App. Br. 5).

Appellant argues that "Cosman repeatedly states that simultaneous delivery of ablation energy to the cluster of electrodes allows the electrode cluster to become a larger, coherent electrode, so that the heating effect is similar to that accomplished by a single electrode" (App. Br. 5). Based upon Cosman's teaching, Appellant contends "Cosman does not suggest to one of ordinary skill in the art that the stereotactic device disclosed in Cosman be used to generate compound lesions but quite the opposite--a single larger lesion" (App. Br. 6).

Appellant argues that "nowhere does Cosman disclose, teach, or suggest that the same ablation probe can be guided through different

apertures in the stereotactic device to create a compound lesion in the manner required by independent claim 23" (App. Br. 7). In addition, Appellant contends that "the entire disclosure of Cosman revolves around the formation of electrode arrays by guiding multiple electrodes through an alignment device, thereby seemingly excluding, or at the least teaching away from, any methodology wherein the same ablation probe is guided through different apertures in an alignment device" (App. Br. 7).

Regarding the obviousness of a cannula with a deployable electrode, Appellant argues that "not only does Cosman fail to suggest the use of cannulae with deployable electrodes, such a modification would defeat the objective set forth in Cosman" (App. Br. 8).

In view of these conflicting positions, we frame the obviousness issues before us as follows:

(1) Would it have been obvious to an ordinary practitioner to use the device of Cosman to perform sequential ablations as in claims 23 and 35?

(2) Would it have been obvious to an ordinary practitioner to use a cannula as described by Cosman to deploy the electrodes for ablation as required in claim 70?

Findings of Fact

1. Cosman teaches a "procedure for using clusters or multiple arrays of electrodes arranged in a configuration for producing large ablation volumes in body tissue" (Cosman 3:50-53).

2. Cosman discloses that the ablation device has a plurality of apertures (*see* Cosman 7:21-22, fig. 1, element 14A).

3. Cosman teaches that the alignment device with apertures is located outside the body, noting that electrodes "are guided in guide block 224 which could be stereotactically placed to aim at tumor T . . . . Guide holes 225, 226, and 227 in block 224 are provided to plan, organize and guide electrode insertions" (Cosman 15:31-36, fig. 10).

4. Cosman teaches guiding the probes to the targeted regions, stating that the "electrode cluster is inserted percutaneously and in unison into the liver of a living patient under CT and ultrasound guidance" (Cosman 11:9-11).

5. Cosman discloses that it was known that ablation can be performed in a sequential manner, but comments that "applying the same radiofrequency voltage simultaneously to a cluster of electrodes accomplishes heat ablation effects vastly different from and far superior to heat ablation effects accomplished by applying the same voltage sequentially or serially to the same number of single electrodes (not in a cluster)." (Cosman 4:23-28).

6. Cosman teaches placement of the electrodes into tubes (cannulae), where the "two electrode shafts ... may be stiff metal tubes for insertion into the body, either percutaneously or intraoperatively" (Cosman 12:26-28).

7. Cosman expressly states that for "percutaneous insertion, pointed electrodes or pointed guide cannulae followed by round-tipped electrodes may suit the clinical technique" (Cosman 16: 13-15).

8. Cosman teaches that the system is inserted "through the skin" (Cosman 3:40).

Discussion of 35 U.S.C. § 103(a) rejection over Cosman

The Examiner and Appellant agree that the prior art discloses compound ablation using "serially or sequentially activated probes" (Rep. Br. 2). Where they disagree, is whether it would have been obvious to modify Cosman to use serially or sequentially activated probes, since Cosman expressly prefers simultaneous ablation which he deems "far superior to heat ablation effects accomplished by applying the same voltage sequentially or serially to the same number of single electrodes (not in a cluster)." (Cosman 4:25-28).

We conclude that the Examiner has set forth a prima facie case that claims 23 and 35 would have been obvious to the ordinary artisan in view of Cosman. Cosman teaches an alignment device for compound ablation, including targeting the device to form lesions (FF 1-4). Cosman discloses that serial or sequential targeting for ablation can be performed (*see* FF 5).

We reject Appellant's argument that Cosman teaches away from the combination serial ablation with the alignment device simply because Cosman prefers performing a single ablation (FF 5). While Cosman does not prefer serial or sequential targeting, it is well settled that, "in a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.'" *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976) .) Thus, "[a]ll the disclosures in a reference must be evaluated, including nonpreferred embodiments, and a reference is not

limited to the disclosure of specific working examples." *In re Mills*, 470 F.2d 649, 651, CCPA 1972) (citations omitted).

We also reject Appellant's argument that the use of a single probe sequentially applied through multiple apertures would have been unobvious (Rep. Br. 4). As the Supreme Court noted, a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 71 S.Ct. 127, 152 (1950). Here, Cosman's teaching of sequential and serial ablation combined with Cosman's teaching of multiple guide apertures to result in sequentially placing a single probe through multiple guide apertures is a "predictable use of prior art elements according to their established functions." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). To conclude that the skilled artisan, aware from the prior art of sequential and serial ablation, would have been unable to combine this technique with the guides of Cosman is inconsistent with the *KSR* teaching that a "person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007).

We also agree with the Examiner that the use of a cannula is taught by Cosman as required by claim 70 (FF 7). Appellant argues that "it can be appreciated from a reading of the entire disclosure that there is no suggestion in Cosman, and in fact a teaching against, guiding a cannula with deployable electrodes through the apertures of the stereotactic device" (App. Br. 10). This argument relies upon a statement by Cosman that "[w]hen the diameter

reaches 3 to 4 mm for such a central cannula, there is the disadvantage of increased risk of hemorrhage and/or great pain or discomfort to the patient during insertion of the large central cannula into the tissue" (Cosman 3:25-29). However this argument is inconsistent with the disclosure of Cosman, because while Cosman chooses not to use a cannula in certain embodiments, in other embodiments Cosman expressly teaches the use of cannulae (*see* FF 6-7). As the Examiner notes, Cosman "specifically disclose[s] an embodiment (Figure 7) that includes a sheath or cannula, to deploy a smaller number of electrodes to a tumor" (Ans. 7). In discussing figure 7, Cosman expressly teaches placement of the electrodes into tubes (cannulae), where the "two electrode shafts . . . may be stiff metal tubes for insertion into the body, either percutaneously or intraoperatively" (Cosman 12:26-28). Finally, Cosman expressly states that for "percutaneous insertion, pointed electrodes or pointed guide cannulae followed by round-tipped electrodes may suit the clinical technique" (Cosman 16: 13-15). *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) ("[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.").

We also are not persuaded by Appellants' argument that Cosman teaches away from alignment of the ablation device on the skin. We think it is reasonable that if the device is placed through the skin, then it is also affixed to the skin as in claim 76, at least by the electrodes themselves (*see* FF 8). Appellants' interpretation of the claim limitation "affixed to the skin" fails to apply the broadest reasonable interpretation of "affixed", which includes the situation when the electrodes affix the alignment device by their

contact with the tissues, including the skin tissues (FF 8). interpretation issue *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) ("[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.").

Further, Cosman's references to percutaneous insertion will result in affixing the device to the skin (*see* Cosman 11:9, 15:1-2, 16:13). Like our appellate reviewing court, "[w]e will not read into a reference a teaching away from a process where no such language exists." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006).

We affirm the rejection of claims 23, 35, 70 and 76 as obvious over Cosman. Claims 24-29, 33, 34, 36-44, 48, 71-75, 77-81 fall with claims 23, 35, 70 and 76 as they were not separately argued.

B. 35 U.S.C. § 103(a) rejection over Cosman and Morris

Claims 28 and 40-43 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Cosman and Morris.

The Examiner relies on Cosman as discussed above. The Examiner relies on Morris to reach the limitations of claims 28 and 40-43, drawn to bosses or recesses in the apertures, which ultimately depend from claims 23 and 35. We will affirm this rejection since Appellants do not separately argue these claims and rely upon overcoming the primary rejection of Cosman, which was affirmed above.

CONCLUSION

In summary, we affirm the rejection of claims 23, 35, 70 and 76 under 35 U.S.C. § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 24-29, 33, 34, 36-44, 48, 71-75, 77-81 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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